

United States Senate

WASHINGTON, DC 20510

December 23, 2020

The Honorable Stephen Hahn, MD, Commissioner
Food and Drug Administration
10903 New Hampshire Avenue,
Silver Spring, MD 20993

Dear Commissioner Hahn,

We write to encourage the Food and Drug Administration (FDA) to continue working with vaccine manufacturers and health care providers to clarify and ensure that any extra doses of COVID-19 vaccine found within individual vials are appropriately used if it is determined that it is safe to do so. We also request information on steps the FDA is taking to minimize COVID-19 vaccine waste going forward.

Last week, we saw the first shipments of approximately 2.9 million doses of the Pfizer COVID-19 vaccine delivered across the country, representing a significant milestone in our country's efforts to end this pandemic.¹ While the Pfizer vaccine's label and the FDA's emergency use guidelines for the vaccine indicate that each vial contains five doses, pharmacists administering the vaccines have reported that in some instances the vials have enough medication to provide six or seven vaccine doses.² Absent clarifying guidance about the safety or permissibility of using any such additional doses, reports indicate that hospitals and pharmacies may have thrown away extra doses of the Pfizer vaccine at a time when this critical vaccine is in short supply and our country is recording an average of 215,000 new coronavirus cases per day.³

As we work to ensure the safe administration of COVID-19 vaccines, it is imperative that we do not waste available doses, especially while initial supply is limited and demand remains high. According to experts, manufacturers often overfill vaccine vials to protect against spills and accommodate the dilution process, and Pfizer has indicated that the amount of vaccine remaining in a vial after five doses can vary depending on the type of needles and syringes used.⁴ It is estimated that the availability of these extra doses in the Pfizer vaccine vials could expand our country's supply of the vaccine by as much as 40 percent.⁵ Expanding our supply of the vaccine

¹ Thomas, K. (Dec. 16, 2020). *Hospitals Discover a Surprise in Their Vaccine Deliveries: Extra Doses*. New York Times. <https://www.nytimes.com/2020/12/16/health/Covid-Pfizer-vaccine-extra-doses.html>.

² Goldhill, O. (Dec. 16, 2020). *Labeling Confusion Led to Wasted Doses of Pfizer Covid-19 Vaccine in First Days of Rollout*. STAT. <https://www.statnews.com/2020/12/16/labeling-confusion-led-to-wasted-doses-of-pfizer-covid-19-vaccine-in-first-days-of-rollout/>; Food and Drug Administration (Dec. 11, 2020). *Letter to Pfizer Inc. Authorizing the Emergency Use of the Pfizer-BioNTech COVID-19 Vaccine*. <https://www.fda.gov/media/144412/download>; Owerhohle, S. (Dec. 16, 2020). *FDA says Pfizer Vaccine Vials Hold Extra Doses, Expanding Supply*. Politico. <https://www.politico.com/news/2020/12/16/pfizer-vaccine-extra-doses-447117>.

³ Thomas, K. (Dec. 16, 2020). *Hospitals Discover a Surprise in Their Vaccine Deliveries: Extra Doses*. New York Times. <https://www.nytimes.com/2020/12/16/health/Covid-Pfizer-vaccine-extra-doses.html>.

⁴ Owerhohle, S. (Dec. 16, 2020). *FDA says Pfizer Vaccine Vials Hold Extra Doses, Expanding Supply*. Politico. <https://www.politico.com/news/2020/12/16/pfizer-vaccine-extra-doses-447117>.

⁵ Owerhohle, S. (Dec. 16, 2020). *FDA says Pfizer Vaccine Vials Hold Extra Doses, Expanding Supply*. Politico. <https://www.politico.com/news/2020/12/16/pfizer-vaccine-extra-doses-447117>.

is crucial in light of recent reports that we may face vaccine shortages in the future due to manufacturing constraints and global competition for limited vaccine doses.⁶

We appreciate your swift action to evaluate this issue and clarify whether excess doses of the Pfizer vaccine found in individual vials may safely be used. We also encourage you to continue offering guidance and support to vaccine manufacturers and health care providers to ensure that guidelines for future authorized coronavirus vaccines account for the possibility that vials may contain extra doses beyond the labeled amount. We also respectfully request that you respond to the following questions regarding steps the FDA is taking to minimize vaccine waste going forward:

1. What steps is the FDA taking to ensure that emergency use guidance and vaccine labeling for future authorized COVID-19 vaccines consider and clarify whether vials containing additional doses beyond the labeled amounts can be safely administered?
2. A strong federal strategy for distributing the COVID-19 vaccine includes making sure that minimal amounts of the vaccine go to waste, while monitoring the safety of the administration process. What clinical monitoring systems does the FDA have in place to assess how these vaccines are being administered in order to respond to issues regarding vaccine waste? Additionally, how will the FDA work with other federal, state, Tribal, and local agencies to ensure that the second round of distributed vaccine doses are enough for all individuals to receive their second dose in a timely manner?
3. How does the FDA work with other agencies, like the Centers for Disease Control and Prevention (CDC), to support states and health care providers in ensuring that they are informed on best practices for administering these vaccines to minimize waste?

Sincerely,

/S/ Amy Klobuchar
Amy Klobuchar
United States Senator

/S/ Dick Durbin
Richard J. Durbin
United States Senator

/S/ Robert Menendez
Robert Menendez
United States Senator

/S/ Margaret Wood Hassan
Margaret Wood Hassan
United States Senator

/S/ Elizabeth Warren
Elizabeth Warren
United States Senator

⁶ Oweremohle, S. (Dec. 8, 2020). *U.S. Could Face Months of Vaccine Shortages Amid Global Competition*. Politico. <https://www.politico.com/news/2020/12/08/coronavirus-vaccine-shortage-443839>.